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MITRA, RITA

ART UNIT	PAPER NUMBER
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,270	NAKAJIMA ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-45* is/are pending in the application.

4a) Of the above claim(s) *29,31-43 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28, 30, 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicants' amendment in response to office action dated March 13 2006, filed on June 13, 2006 is acknowledged. Claims 1-19 have been canceled. New claims 20-45 have been added. Claims 29, 31-43 and 45, and SEQ ID NOs: 3 and 4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Therefore, claims 20-28, 30 and 44, and SEQ ID NOs: 1 and 2 are currently under consideration.

The rejection of claims 1-19 in previous office action is moot because claims have been canceled.

New Ground(s) of Rejection

Objection to Specification

The disclosure is objected to because of the following informalities:

1) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See specification page 26, last paragraph and page 27, first paragraph. Please drop http:// from the hyperlink.

2) The title of the invention is objected to because of using the word "novel". It should be noted that novelty is a determination of the office not an assertion by Applicants.

3) Continuity data needs to be entered on page 1, line 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 21, 25, 26, 30 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a polypeptide comprising a nucleotide sequence as set forth in SEQ ID NO: 1, does not reasonably provide enablement for the DNA sequence comprising a nucleotide sequence having at least 96% sequence identity to the sequence of SEQ ID NO: 1 or fragments and variants of the sequence of SEQ ID NO: 1; and the polypeptide encoded therein (SEQ ID NO: 2). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404).

The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 20, 21, 25, 26, 30 and 44, directed to an isolated polynucleotide encoding a polypeptide protein, having an amino acid sequence of SEQ ID NO: 2 and fragments and derivatives thereof, wherein said polypeptide sequence hybridizes with a full complement of SEQ ID NO: 1 or fragment thereof; wherein a vector and a transformant comprising the polynucleotide of claim 20. Claim 44 is drawn to a composition comprising polynucleotide of claim 30 suitable for administration as an antisense medication.

In the instant case, the amount of experimentation is enormous since the number of changes from the specific sequence are large, one of skill in the art would have to make and test each one to determine if it had the activity of the parent protein. The amount of guidance presented is limited to the exact sequence. No discussion is present as to where the changes might be made to SEQ ID No: 1, much less any sequence that encodes SEQ ID No: 2. An example of desirable guidance for a DNA encoding a protein would be disclosure of the sequence of exons and introns, regulatory sequences, binding sites for transcription factors, active sites in the coding sequence. These are not present. The nature of the invention is a new DNA sequence corresponding to a polypeptide. The art is unpredictable. The effect of one or a few conservative substitutions might be somewhat predictable, if the active areas of the molecule were known, but more changes than that, are less predictable. The number of changes to result in a sequence with 96% identity to the starting sequence would, of course, be 4 changes per hundred nucleotides. The effect on function of this many changes is clearly unpredictable. Finally, these claims are very broad in the sense that many millions of different proteins fall within the scope of the claims.

Based on this analysis, the finding of undue experimentation is mandated.

Applicants have not recited the conditions under which the hybridizations are to take place in the claims. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization without a clear and explicit recitation of the conditions associated with the hybridization. For example, the definition of stringency as it pertains to hybridization conditions is subject to

interpretation and is different from laboratory to laboratory. Therefore, without a clear and explicit recitation of the conditions, which were actually used by Applicants in isolating the claimed polynucleotides which hybridize to the disclosed sequences, the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention. Without such guidance, the experimentation left to those skilled in the art is undue. This rejection would be overcome by amending the claims to recite one of the hybridization conditions listed on page 14 of the specification.

Also, there is no guidance provided by the specification on how to use the polypeptides fragments and variants. The specification does not describe how to determine if said fragments and variants still have functional activity, in particular, whether or not they retain their presumed role in sugar production. Further, the specification does not describe at all how to determine what changes and where in the polypeptide sequence would result in a "different" than the corresponding amino acid sequence in SEQ ID NO: 2 (claims 25 and 26). Moreover, the specification is totally devoid of any working examples of polypeptides fragments and variants. The specification merely compares SEQ ID 2, a 35 kd human protein, and its binding to substance WF00144. There is prior art to the polypeptides of having more than 90% sequence homology to SEQ ID NO:2; the relative level of skill in this art is very high; the predictability of the art is low with regard to the determination of the function of any of these polypeptides and whether they retain their functional properties, particularly their involvement in sugar production.

Claim 30 is also not enabled because of the limitation “consisting of at least 15 consecutive bases”. It would require undue experimentation to determine which of the many possible fragments of sequence in SEQ ID NO: 1 might have any function at all. The specification is silent as to how to use any such fragment and thus these claims are not enabled.

If the product claim 30 is not enabled, the composition claim 44 comprising product of claim 30 is also not enabled.

Based on this analysis, the finding of undue experimentation is mandated.

Claim Rejections - 35 USC § 112, First Paragraph, Written description

Claims 20, 21, 25, 26, 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotide sequence with 96% identity to the base sequence of SEQ ID NO: 1. The claimed invention does not meet the current written description requirements for the following reasons. Firstly, substantial variation in structures and functions are expected among polypeptides that share 96% sequence identity to SEQ ID NO: 1. Further, the disclosure of SEQ ID NO: 1 does not provide adequate written description for all polynucleotides having at least 96% sequence identity to SEQ ID NO: 1. Since Applicant does not have any representative examples of a single species of the polynucleotides of claims 20, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms. Given this lack of disclosure, Applicant's written description of the claimed invention is insufficient to show that Applicants were in possession of the full scope of the claimed invention.

Claims 25 and 26 are drawn to a polynucleotide encoding an amino acid sequence of SEQ ID NO: 2 where one and upto 10% of the amino acid residues described by SEQ ID NO: 2 are different than the corresponding amino acids in SEQ ID NO: 2.

The claimed invention does not meet the current written description requirements for the following reasons. Firstly, substantial variation in structures and functions are expected among polypeptides that have been randomly mutated with one or more amino acids at various portions of the protein sequence of SEQ ID NO: 2. Secondly, the disclosure of the 35 kd protein does not provide adequate written description for all polypeptides where one or a few amino acids are substituted, deleted, inserted and/or added in SEQ ID NO: 2. Since Applicant does not have any representative examples of a single species of the polypeptides of claims 25 and 26, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms. Given this lack of disclosure, Applicants' written description of the claimed invention is insufficient to show that Applicants were in possession of the full scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21 (2) of such treaty in the English language.
b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 21, 22, 24, 27, 28 are rejected under 35 U.S.C. 102(a) and (e) as being clearly anticipated by Tang et al. and Strausberg et al.

Tang et al. (US 60/336,453) disclose a polynucleotide sequence (sequence 103) with 96.6% sequence identity to the elected polynucleotide of the invention designated as SEQ ID NO: 1. This clearly anticipates claims 20, 21, 22, 24, 27, 28 under 102 (a)

Tang et al. (US 60/336,453) disclose a polynucleotide sequence encoding a protein that comprises an amino acid sequence of SEQ ID NO: 2 with 99.6% sequence identity to the peptide of the invention designated as SEQ ID NO: 2. This clearly anticipates claim 20, 23, 25, 26 under 102(e).

Stausberg et al. (2002) disclose a polynucleotide sequence (accession BC045550) with 96.6% sequence identity to the elected polynucleotide of the invention

designated as SEQ ID NO: 1. This clearly anticipates claims 20, 21, 22, 24 under 102 (a).

Strausberg et al. (2002) disclose a polynucleotide sequence encoding a protein that comprises an amino acid sequence of SEQ ID NO: 2 with 100% sequence identity to the elected peptide of the invention designated as SEQ ID NO: 2. This clearly anticipates claims 20, 23, 25, 26 under 102(e).

Applicants have stated at page 9 that this rejection using Tang reference would not apply to the new claims, which require that the polynucleotide encodes a polypeptide that binds to WF00144. This argument is not persuasive because the property of binding is inherent.

Similar consideration is applied to Strausberg because this reference teaches a polynucleotide that has 96.6% sequence identity to SEQ ID NO: 1, wherein the polynucleotide encoding a protein that comprises an amino acid sequence which has 100% sequence identity to SEQ ID NO: 2

Claims 21 and 30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Valenzuela et al. (2000).

Claim 21 as reads on glycine.

Valenzuela et al. (2000) disclose a polynucleotide sequence (accession AAA93103) with 100% sequence identity to the base sequence complementary to the elected polynucleotide of the invention designated as SEQ ID NO:l, and having at least 19 bases. This clearly anticipates claims claim 30 under 102(b).

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Mitra, Ph.D.

September 1, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER